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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,391	03/26/2001	Minoru Fujimori	2001-0206A	7242

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

23

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/816,391	FUJIMORI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Brian Whiteman	1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

a)  The period for reply expires 5 months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) 22 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 22.

Claim(s) objected to: 32.

Claim(s) rejected: 3-5,8-14,16,19-21,24 and 28-31.

Claim(s) withdrawn from consideration: 6,7,15,17,18,23,25 and 27.

8.  The proposed drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s) ( PTO-1449) Paper No(s). \_\_\_\_\_.

10.  Other: See Continuation Sheet

Continuation of 5. does NOT place the application in condition for allowance because: The 112 first paragraph enablement rejection for claims 3-5,8-14,16,19-21,24 remains. The arguments are not found persuasive for the reasons set forth in the non-final and final rejections. In addition, the US Patent 5,601,999 cited in the argument is directed to an anti-tumor agent and the disclosure of the Patent does not use the same methods or materials as set forth in the claimed invention. Furthermore, the post-filing reference (Li, Cancer Gene Therapy, 2003:10:105-111) cited in the argument displaying that one species of the claimed species of *Bifidobacterium* can be used in the claimed invention does not overcome the unpredictability of efficiently transforming the other claimed *Bifidobacterium* species (See Argani and Yazawa).

In addition, the court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment..., they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [footnote omitted].

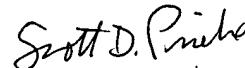
Thus, in view of the In Re Wands Factors, the specification does not provide sufficient guidance for one skilled in the art to make and use the full scope of the claimed invention.

The Declaration filed on 5/2/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(a) rejection as anticipated by Yazawa et al. (claims 3, 8, and 9) or the 102(a) rejection as anticipated by Babinocova (claims 3, 4, 8, and 9) or the 103(a) rejection for claims 3-5, 8,9, 12, 14, 16, 19, 21, 24, and 28-31 as being unpatentable over Babinocova taken with Tagliabue.

The Declaration only establishes that the Yazawa et al. article is a 102(a) reference. The Yazawa publication has a different inventive entity than the entity in the instant application because the Yazawa's publication lists five of the seven inventors listed in the application. The Office assumes that all of the inventors, absence evidence to the contrary, are the inventors of the application. The Declaration has not provided evidence that the seven inventors reduce the invention to practice before the five inventors listed on the Yazawa publication.

Continuation of 10. Other: This application contains claims 6, 7,15, 17,18, 23, 25, 27 drawn to a non-elected invention or species without traverse in Paper No.13 or because of the amendment to the claims. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 32 is objected to as being dependent upon a rejected base claim (claim 28), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER